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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

21

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Applicant No.

09/722,441

Applicant(s)

HANKE ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-29 and 61-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-5, 16, 18-29, 61, 62, 64-66 and 73-79 is/are allowed.
- 6) ☒ Claim(s) 6-15 and 67-72 is/are rejected.
- 7) ☒ Claim(s) 63 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a Final rejection (Paper No. 18, mailed on December 17, 2002), Applicants filed an amendment along with a request for continued examination (RCE) received on March 17, 2003 (Paper Nos. 20 and 21). Said amendment cancelled Claims 1, 17, and 30-60 and amended Claims 8, 9, 16, and 63, and added new Claims 68-79. Thus, Claims 2-16, 18-29, and 61-79 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, a request for the benefit of priority for the U.S. Provisional Application Nos. 60/173,707, filed on December 30, 1999, and 60/184,130, filed on February 22, 2000, as requested in the first lines of the specification, is acknowledged.

### ***Drawings***

3. As previously noted, the formal drawings filed on June 22, 2001 (Paper No. 5) and on September 23, 2002 (Paper No. 15) have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

### ***Withdrawn - Objections to the Specification***

4. Previous objection to the specification because the title is not adequately descriptive is withdrawn by virtue of Applicants' amendment.

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5. Previous objection to the specification because the abstract does not adequately describe the disclosed subject matter (see M.P.E.P. § 608.01(b)) is withdrawn by virtue of Applicants' amendment.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph***

6. Previous rejection of Claims 8, 9, 16, 25, and 26 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms “ ‘lysA’ ” and “ORF2” is withdrawn by virtue of Applicants' amendment deleting reference to the sequences when not accompanied by a SEQ ID NO.

7. Previous rejection of Claim 63 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “operably directly linked to the encoded polypeptide sequence” is withdrawn by virtue of Applicants' amendment.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph***

8. Previous rejection of Claims 16, 25, and 26 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment defining the structure and function of the additional genes within the claimed polynucleotide.

***Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph***

9. Previous rejection of Claims 8 and 9 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that all the amendment to “expresses...aspartate-

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semialdehyde dehydrogenase activity”, for example, obviates the instant rejection. This is not the case.

As previously noted,

“These polypeptides [activities] are functionally described in the specification in Figure 1 (except for ‘*lysA* and *ORF2* as noted in a previous rejection). Moreover, a single species of each of these polypeptides [activities] (except for *lysA* with two disclosed species) is structurally described in the figures. Thus, a single species (or two in the case of *lysA*) of the genus of each named gene is fully described. However, a description of the common characteristics of each genus, particularly a correlation between the structure and function of these genes [encoding the claimed activities], is lacking in the specification. Without such a correlation, one of skill in the art would be unable to identify other members of each genus in structural and functional terms. In particular, the structure of the other members of each genus is unpredictable based on the description in the specification.”

Thus, it is clear from the previous rejection that a single species of the claimed genus does not adequately describe the genus as argued by Applicants.

## NEW OBJECTIONS/REJECTIONS

### *Claim Objections*

10. Claims 8-9 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 attempts to further limit the subject matter of Claim 6 drawn to a method using a *Corynebacterium* host cell. The addition of any one of the activities (a-e) does not further limit the method because *Corynebacterium* species already contain the activities listed.

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11. Claim 63 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 63 attempts to further limit Claim 61 by requiring “operably linked”; however, Claim 61 already requires that the promoter drive expression of the encoded polypeptide, which is equivalent to operable linkage.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 6-15 and 67-72 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 6 and 67, it is unclear what kind of method is being claimed. The Examiner inserting after method ---for transforming a Corynebacterium species host cell--- for clarity.

13. Claims 8-9 and 68-72 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 8, the phrase “expresses one of the following...activity” is unclear. Firstly, it is unclear how an activity is “expressed”; in the art, polypeptides are expressed and activities are merely a part of the host cell’s characteristics. Clarification is required.

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Secondly, the Examiner notes that previous Claim 8 was drawn to having at least one of the following polypeptides (activities) while the pending Claim 8 is drawn to having only one additional activity. It is unclear how *Corynebacterium*, which natively contain all these activities, are to be found to be used in the instant methods.

14. Claims 68-72 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The antecedent basis of "said activity" is unclear since all the activities are defined separately in Claim 8. The Examiner suggests amending Claim 8 to ---wherein said host cell expressed at least one of the following activities:---.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 68-72 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are rejected for the same reasons maintained above against Claims 8-9.

***Summary of Pending Issues***

16. The following is a summary of the issues pending in the instant application:
- a) Claims 8-9 and 63 stand objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
  - b) Claims 6-15 and 67-72 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to clarify what kind of method is being claimed.
  - c) Claims 8-9 and 68-72 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “expresses one of the following...activity”.
  - d) Claims 68-72 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of “said activity”.
  - e) Claims 8, 9, and 68-72 stand rejected under 35 U.S.C. § 112, first paragraph, written description.

Attention to **all** the above issues is required in response to the instant Office action to be fully responsive to this communication.

***Allowable Subject Matter***

17. As previously noted, Claim 2 is drawn to a polynucleotide molecule encoding a mutant aspartokinase gene (the polypeptide SEQ ID NO: 2 is encoded by the polynucleotide SEQ ID NO: 1), which differs from the wild-type *Corynebacterium glutamicum* sequence at position 380 (T380I). This mutation renders the aspartokinase more resistant to feedback inhibition by lysine than the wild-type enzyme. This mutant gene was isolated from ATCC 21529, which strain is described in USPN 3,708,395 (Nakayama *et al.* 1973, IDS ref. AF1). While numerous *C. glutamicum* aspartokinase lysine-feedback-resistant mutants are known, for example see EP 0



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854 189 A2 (IDS ref. AM1), the T380I mutation in *C. glutamicum* described in the instant application is novel and not obvious in view of the prior art. The novelty of a polynucleotide encoding SEQ ID NO: 2 governs the novelty of all the pending claims. All other specific examples of lysine biosynthetic pathway genes described in the figures are known in the art. The promoter of SEQ ID NO: 17 is also known as an endogenous promoter of the *lysA* gene in *C. glutamicum* (see Marcel *et al.* IDS ref AS5).

### **Conclusion**

18. Claim 63 is objected to; Claims 6-15, and 67-72 are rejected. Claims 2-5, 16, 18-29, 61, 62, 64-66, and 73-79 are allowed. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

May 26, 2003

